

Appl. No. : **09/787,356**
Filed : **June 25, 2001**

REMARKS

Claims 1 and 6, have been amended and Claims 3, 4, and 10-19 have been cancelled without prejudice. As a result, Claims 1, 2, 5-9 and 20 are now pending in the present application. Support for the amendments is found in the specification and claims as filed. Specific support for Claim 20 can be found in the specification as filed at page 7, lines 2-5 and 17-21, as well as in the various examples at the end of Applicants' specification. Accordingly, the amendments do not constitute the addition of new matter. Reconsideration of the application in view of the foregoing amendments and following comments is respectfully requested.

Amendment of Title

The Examiner objected to the title as not being descriptive. Applicants have amended the title to METHODS OF TREATING AIRWAY DISEASES BY ACTIVATING PAR.

Accordingly, Applicants respectfully request the Examiner to reconsider and withdraw this objection.

Objections to Specification

The Examiner objected to the specification because it was not arranged properly. A substitute specification that is properly arranged is filed herewith. No new material has been added to the substitute specification.

The Examiner objected to the specification because the section containing a brief description of the drawings at page 24 is inconsistent. This section has been amended for consistency.

The Examiner objected to the specification because there are two Figure 38's and two Figure 36's. Applicants have amended the figures to be consistent. The first Figure 38 (Panel 29/41) has been amended to recite "FIGURE 27." The first Figure 36 (Panel 37/41) has been amended to recite "FIGURE 35."

The Examiner objected to the specification because the specification does not contain an abstract. An abstract is included in the substitute specification. The abstract was included in the

Appl. No. : **09/787,356**
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original PCT application that was filed at the U.S. national phase. The abstract was located on the cover page of the PCT application.

Accordingly, Applicants respectfully request the Examiner to reconsider and withdraw the objections to the specification.

Objections to Claims

The Examiner objected to Claims 6 for syntax. Applicants have amended Claim 6 to recite "SEQ ID NO:2 or SEQ ID NO:3." Accordingly, Applicants respectfully request the Examiner to reconsider and withdraw this objection.

The Examiner's rejection of Claims 10-19 are now moot in view of the cancellation of those claims. Accordingly, these rejections will not be further addressed hereinbelow.

Rejection of Claims under 35 U.S.C. § 112, scope enablement

The Examiner rejected Claims 1-19 under 35 U.S.C. § 112, first paragraph, because the Examiner believes that the Specification does not reasonably provide enablement for methods and compositions of prophylaxis of bronchoconstriction or for treatment or prophylaxis of any and all airway diseases.

Applicants have amended Claim 1 to recite, *inter alia*, "[a] method for a prophylaxis or a treatment of inflammation of an airway of an animal." Applicants have amended Claims 13 and 15 to recite, *inter alia*, "inhibition of inflammation." Support for this amendment can be found in the Specification at pages 77-78. Accordingly, Claims 1-19 are enabled by the Specification at pages 77-78 which disclose lung inflammation studies.

The Examiner rejected Claims 6-9 under 35 U.S.C. § 112, first paragraph for reciting "functional equivalents, homologues, and derivatives." The Examiner believes that the Applicant provided no guidance for "functional equivalents, homologues, and derivatives."

Applicants have amended Claim 6 to remove the term "functional equivalents, homologues, and derivatives."

Appl. No. : **09/787,356**
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Accordingly, Applicants respectfully request the Examiner to reconsider and withdraw the rejections under 35 U.S.C. § 112 with regards to scope enablement.

Rejection of Claims under 35 U.S.C. § 112, written description

The Examiner rejected Claims 6-19 under 35 U.S.C. § 112, first paragraph, because the Examiner believes that these claims are genus claims. The Examiner believes that Applicants have not provided adequate written description of any “compositions” other than the proteins of SEQ ID NO:1, 2, and 3.

Applicants have amended Claim 6 to recite, *inter alia*, “[t]he method according to Claim 1 wherein the agent is a peptide comprising the sequence of SEQ ID NO. 2 or SEQ ID NO:3.” The term “functional equivalents, homologues, and derivatives” has been removed from Claim 6.

Accordingly, Applicants respectfully request the Examiner to reconsider and withdraw the rejections under 35 U.S.C. § 112 with regards to written description.

Rejection of Claims under 35 U.S.C. § 112, second paragraph

The Examiner rejected Claims 1-9 under 35 U.S.C. § 112, second paragraph for the phrase “for a time.” Applicants have amended Claim 1 to remove this phrase.

Accordingly, Applicants respectfully request the Examiner to reconsider and withdraw the rejections under 35 U.S.C. § 112, second paragraph.

Rejection of Claims under 35 U.S.C. § 102

The Examiner rejected Claims 1, 3-6, and 10-19 under 35 U.S.C. § 102(b) as being anticipated by Cicala et al. (Br. J. Pharmacol.).

Cicala et al. discloses that “thrombin might play a role in bronchial asthma through a mechanism...that involves the activation of PAR-1 receptors.” Cicala discloses only the use of thrombin as an activator of PAR-1. Cicala et al. does not disclose PAR2 activation.

According to M.P.E.P. 2131, a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.

Appl. No. : 09/787,356
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Claim 1 has been amended to be directed to PAR-2 activation. Accordingly, the presently pending claims are directed to PAR2 activation. Cicala et al. does not disclose effects of PAR2 activity. Accordingly, the presently pending claim is not anticipated by Cicala et al.

Accordingly, Applicants respectfully request the Examiner to reconsider and withdraw the rejection under 35 U.S.C. § 102(b).

Rejection of Claims under 35 U.S.C. § 103

The Examiner rejected claims 1-19 under 35 U.S.C. § 103(a) as being unpatentable over Cicala et al. (Br. J. Pharmacol.).

Cicala et al. discloses that "thrombin might play a role in bronchial asthma through a mechanism...that involves the activation of PAR-1 receptors." Cicala discloses only the use of thrombin as an activator of PAR-1. Cicala et al. does not disclose PAR2 activation.

According to M.P.E.P.2143.03, to establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art.

As stated above, Claim 1 has been amended to be directed to PAR-2 activation for treatment or prophylaxis of inflammation of the airways. Accordingly, the presently pending claims are directed to PAR2 activation. Cicala et al. does not teach or suggest any effects of PAR2 activity. In fact, it is the Applicants' discovery that PAR2 is present in airway epithelium. Cicala et al. would not teach or suggest to one skilled in the art the usefulness of affecting PAR2 for any purpose, much less for treatment or prophylaxis of inflammation of the airways, since Cicala et al. is silent with respect to PAR2. Accordingly, the presently pending claims are patentable over Cicala et al.

Accordingly, Applicants respectfully request the Examiner to reconsider and withdraw the rejections under 35 U.S.C. § 103(a).

CONCLUSION

In view of the foregoing amendments and comments, it is respectfully submitted that the present application is fully in condition for allowance, and such action is earnestly solicited.

Appl. No. : 09/787,356
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The undersigned has made good effort to respond to all of the rejections in the case and to place the claims in condition for immediate allowance. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is respectfully invited to call the undersigned in order to resolve such issue promptly.

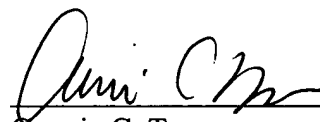
Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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Dated: January 21, 2004

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